

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA**

IN RE: GENENTECH HERCEPTIN)	
(TRASTUZUMAB) MARKETING)	MDL DOCKET NO. 16-MD-2700
AND SALES PRACTICES)	ALL CASES
LITIGATION)	

OPINION AND ORDER

Before the Court is Defendant's Renewed Motion for Leave to Submit Rebuttal Expert Testimony ("Renewed Motion") (Doc. 337).

I. Background

In its January 31, 2018 Opinion and Order, the Court denied Defendant's Motion for Leave to Submit Rebuttal Expert Testimony. (Doc. 294.) At that time Plaintiffs had not yet provided Defendant with any expert testimony in connection with Plaintiffs' forthcoming response to Defendant's Amended Motion for Summary Judgment ("Amended MSJ"). The Court granted Defendant leave to file a renewed motion within five days of receiving Plaintiffs' expert reports, noting that rebuttal expert testimony would be permitted only as to specific evidence that Defendant shows a need to rebut in order to avoid extreme prejudice. (Doc. 321.) On February 20, 2018, Plaintiffs informed the Court that they had provided Defendant with expert declarations. (Doc. 201.) Defendant filed its Renewed Motion on February 21, 2018, and the Court granted Defendant's request for expedited briefing on the Renewed Motion.

II. Analysis

Defendant contends it would suffer extreme prejudice if not allowed to rebut the testimony of one of Plaintiffs' experts, Adalberto Ramirez ("Ramirez"), as to his opinion on Defendant's compliance with current Good Manufacturing Practice ("cGMP") pursuant to 21 C.F.R. § 211.101(a) ("§ 211.101(a)"). Ramirez concludes that of the data he observed relating to batches of

Herceptin 440 mg distributed by Defendant in the United States between 2010 and 2016, “[n]inety percent . . . were below 440 mg,” and opines that this result is “not consistent with cGMP.” (Ramirez Decl., Doc. 337-1, at ¶¶ 26-27, 37.) Specifically, Ramirez cites a Food and Drug Administration (“FDA”) requirement “to formulate with the ‘intent to provide not less than 100 percent of the labeled or established amount of active ingredient.’” (*Id.* at ¶ 35 (citing § 211.101(a)).)

Defendant’s Amended MSJ argues, in part, that Plaintiffs’ state-law claims conflict with FDA regulations permitting “[r]easonable variations” in the contents of a package that are “caused by . . . unavoidable deviations in good manufacturing practice.” 21 C.F.R. § 201.51(g) (“§ 201.51(g)”). Defendant notes that in 1998, FDA approved a Biologics License Application (“BLA”) for its 440-mg vials of Herceptin, determining that the specified content range of (REDACTED) was reasonable. However, Defendant’s Amended MSJ does not address § 211.101(a).

Plaintiffs argue that § 211.101(a) specifies what constitutes “good manufacturing practice” for the purpose of § 201.51(g), and that Defendant therefore could have addressed its cGMP compliance in its Amended MSJ. (Pls.’ Resp. in Opp. to Def.’s Renewed Mot. 3.) Plaintiffs urge the Court to hold Defendant to its prior representation that it could present “all supporting evidence” in its Amended MSJ, which Defendant sought to file early in the litigation, and contend they would be prejudiced by the introduction of a new expert declaration almost two years into Phase I of this case. (*See* Doc. 303-5, at 2.) Plaintiffs also fault Defendant for an “apparently . . . false representation” that Ramirez’s opinion falls outside the expertise of Defendant’s expert David Lin (“Lin”). (Doc. 344, at 4.) Plaintiffs note that Lin lists “current Good Manufacturing Practices (cGMPs)” under the “expertise” section of his curriculum vitae. (*See* Doc. 201-5.)

Defendant argues that the “intent” requirement under § 211.101(a) is unrelated to the “reasonable variations” permitted under § 201.51(g). Defendant notes that § 201.51(g) was

implemented a decade before the current version of § 211.101(a). Defendant therefore disagrees that it could have anticipated a need to address the requirements of § 211.101(a) when it filed its Amended MSJ. Defendant also contends Lin did not opine on cGMP compliance in his declaration and that cGMP is “an extremely broad subject.” (Def.’s Reply in Supp. of Renewed Mot., at 4.)

The parties dispute whether FDA’s “reasonableness” determination in the BLA is constrained by the “intent” requirement of § 211.101(a). Accordingly, the Court finds that it would benefit from an expert’s “testimony setting forth the key elements of FDA’s rules and confirming its interpretive practices” in assessing Defendant’s obstacle preemption argument in its Amended MSJ, as Defendant proposes. (Def.’s Renewed Mot., at 2.) The Court further finds that Defendant has shown it may be severely prejudiced if not permitted to rebut the opinion of Ramirez regarding cGMP compliance.

Plaintiffs have indicated that they may wish to file their response to the Amended MSJ soon and object that any rebuttal expert testimony would “precipitate a new round of discovery, an additional deposition, and a necessary opportunity for Plaintiffs to dispute the evidence proffered by Genentech and its new expert.” (Pls.’ Resp. in Opp. to Def.’s Renewed Mot., at 5.) Any burden on Plaintiffs is not unreasonable, given that under Case Management Order # 3 (Doc. 278), Phase 1 discovery does not close until April 23, 2018, and Plaintiffs’ response to the Amended MSJ is not due until May 22, 2018. However, to prevent any undue prejudice arising from lack of notice and opportunity to respond to evidence, the Court will permit Plaintiffs, within five days of receiving Defendant’s rebuttal expert report, to seek leave to file a surreply responding to any new evidence in Defendant’s reply, if necessary to avoid extreme prejudice. *See Beaird v. Seagate Tech., Inc.*, 145 F.3d 1159, 1164 (10th Cir. 1998) (internal citations omitted) (“Thus, when a moving party advances

in a reply new reasons and evidence in support of its motion for summary judgment, the nonmoving party should be granted an opportunity to respond.”); *see also Teran v. GB Int’l, S.p.A.*, 652 F. App’x 660, 669 n.10 (10th Cir. 2016) (citing *Beaird*).

III. Conclusion

Defendant’s Renewed Motion for Leave to Submit Rebuttal Expert Testimony (Doc. 337) is GRANTED.

SO ORDERED this 6th day of March, 2018.


TERENCE KERN
United States District Judge